

RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
55 Diamond Road Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

Date Issued: 21st April 2021

Complaint Reference: REC513

Action Type: Device Modification

Detail on Affected Devices:

Our records indicate that your facility may have received the following product

Device Name	Catalogue Number	GTIN
RX Imola	RX4900, RX4900R	05055273206104

Reason for Action:

Randox have now released the RX Imola software version UI2550328127 & Unit Main 2550302124 with the following modifications:

Correction:

An issue has been fixed where the software froze during processing of commands.

Improvements:

- Power control voltage improved during operation of SPT liquid level detection.
- Normal range for ISE (U) Potassium (K) accepted up to 999.9 mmol/l.
- Order screen settings applied to reagent blank measurement.
- Alarm messaging updated for temperature sensor RCU 3057,3076 & ASP 3058, 3077

Risk to Health:

Delay in reporting patient results if software froze during operation.

Action to be taken:

- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form 12187-QA to technical.services@randox.com within five working days.
- Please contact your local service provider to arrange for the software update to be performed.

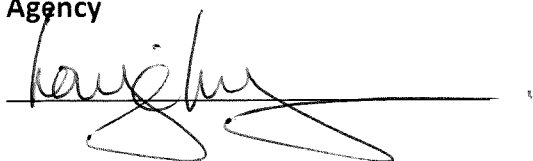
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Transmission of Field Safety Notice: Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. If you have any questions or concerns please contact Radox Technical Services.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency

A handwritten signature in black ink, appearing to read 'K. Hough', is written over a horizontal line.